REMARKS

Claims 1-54 are pending in the application, with Claims 3-5 and 18-54 withdrawn from consideration. Claims 1, 2 and 6-17 are the claims under consideration. Claims 1 and 9 have been amended herein. Claim 1 is the only independent claim under consideration.

Section 112, second paragraph

Claim 9 was rejected under 35 USC 112, second paragraph as indefinite. Claim 9 has been amended herein to now depend from Claim 8, thereby providing proper antecedent basis for the recited "guidewire lumen". Withdrawal of the Section 112 rejection is respectfully requested.

Section 102(b) and 103(a) rejections

Claims 1 and 2 were rejected under 35 USC 102(b) as being anticipated by US Patent 3,948,269 (Zimmer); Claims 6 and 7 were rejected under 35 USC 103(a) as being unpatentable over Zimmer in view of US Patent 4,949,460 (Merry et al.); and Claims 8-17 were rejected as being unpatentable over Zimmer in view of US Patent 5,868,735 (Lafontaine). In view of the foregoing claim amendments, each of the rejections is traversed and reconsideration is respectfully requested.

Independent Claim 1, as amended herein, is directed to a device to treat tissue while preventing tissue damage to adjacent tissue, the device including an ablation catheter, a *tubular* introducer sheath for the ablation catheter, the introducer sheath at least partially contacting tissue to be protected, *wherein the ablation catheter is inserted through and extends past a distal end of the introducer sheath*, a heater disposed adjacent or within the introducer sheath, the heater thermally coupled to the tissue, and a control unit for the heater.

Zimmer is directed to a cryomedical device in which the entire distal end of a closed probe contacts tissue to be rapidly cooled. The exterior surface of probe 1 of Zimmer (what the Action uses to read up Applicants' 'sheath') does *not* "at least partially *contact tissue to be protected*", as recited in Applicants' Claim 1, but rather the shaft portion 5 of probe 1 of Zimmer has a closed *distal end* 2, which "is brought into contact with a body portion or tissue 3" to be cooled. As shown in Figure 1 of Zimmer, the *entire* distal portion 2 of the probe 1 contacts the surface to be treated (or 'cooled') – not tissue 'to be protected'.

In addition, Applicants note that the 'side' portions of the shaft 5 that include "vacuum jacket 6 for thermal insulation" cannot be relied upon as teaching the elements recited in Claim 1 as filed, as those portions of Zimmer's device do not "contact tissue" to be protected.

For each of the foregoing reasons, Applicants submit that independent Claim 1, as filed, is patentable over Zimmer.

However, in order to eliminate any issue as to patentability and to even further distinguish over Zimmer, Claim 1 has been amended herein to recite that the "ablation catheter is inserted through and extends past a distal end of the introducer sheath".

Zimmer provides absolutely no teaching or suggestion of a device to treat tissue that includes an ablation catheter and an introducer sheath, in which the catheter *is inserted through the sheath and extends past a distal end of the sheath*".

For all of the above reasons, it is submitted that independent Claim 1, as amended herein, is *not* anticipated by Zimmer and is patentable thereover.

The teachings of Merry and Lafontaine, cited in the Section 103(a) rejections of dependent Claims 2 and 6-17, similarly fail to teach or suggest the elements of the device defined by amended independent Claim 1 that are lacking in Zimmer. For example, Merry is directed to an apparatus for cryosurgery with the ability to control the rate and degree of freezing. Like the device described in Zimmer, the apparatus of Merry includes "freezing tip 26 *closed at its lower end 26a*" (col. 4, lines 22-24). There is absolutely no teaching or suggestion in Merry to use a sheath, that partially surrounds an ablation catheter that extends therefrom, and that has a heater disposed adjacent or within the sheath, to protect tissue adjacent to the tissue to be treated.

Lafontaine is directed to a catheter and method for preventing reclosure of a lesion following angioplasty by cooling the lesion, thereby killing the cells that would promote restenosis (col. 1, lines 45-55). More specifically, Lafontaine implements a dilatation balloon 14 at the distal end of its shaft 12. The balloon is "advanced across a lesion...is dilated by forcing fluid into the balloon 14...coolant is then released into chamber 42...to cool the adjacent lesion" (col. 4, lines 21-26). The heaters provided in Lafontaine are expressly provided to enable "precise control over the thermal history of the tip by means of control over low power electrical heaters...such control is accomplished in a way that the compensating effects of cooling by the refrigerant and heating by the heating elements is adjusted to achieve positive control over the thermal history of the probe" (col. 3, lines 44-53). Like Zimmer and Merry, there is absolutely no teaching or suggestion in Lafontaine to use a sheath, that partially surrounds an ablation catheter that extends therefrom, and that has a heater disposed adjacent or within the sheath, to protect tissue adjacent to the tissue to be treated.

Dependent Claims 2 and 6-17 are believed to be clearly patentable for all of the reasons indicated above with respect to amended independent Claim 1, from which they depend, and even further distinguish over the cited references by reciting additional limitations.

Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicants' undersigned attorney at (908) 518-7700 in order that any outstanding issues be resolved.

Respectfully submitted,

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I hereby certify that this document and any document referenced herein is being deposited with the US Postal Service as first class mail under 37 C.F.R. 1.8 and addressed to Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on March 24, 2004

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